

wall which defines the interior of the container being coated with a plastics coating which inhibits the pharmaceutically active agent in the suspension from depositing thereon (underlining added for emphasis), and a metering valve which is constructed and which functions according to the claim limitations.

As described at page 2 of Applicants' specification, due to the replacement of the fluorochlorohydrocarbon propellant gases with such alternative propellant gases, the PAA tends to adhere to and build-up on the inner container wall. This presents a problem with proper administration of the PAA, in that such deposits on the inner wall of the container may result in the desired amount of PAA that is to be administered to the user not being present in the metering chamber. A further consequence is that the total amount of PAA stored in the container cannot be administered, since a very considerable proportion of the total amount of the PAA introduced into the container remains deposited on the inner wall of the container.

Applicants have discovered that this problem may be solved by applying to the "inner" wall of the container a plastics coating which inhibits deposition of the PAA thereon. It is critical that the coating be selected such that it inhibits the particular PAA being administered from adhering to the inner wall, and it of course is essential that the coating be applied to the inner surface of the container wall so that it protects the inner wall from the PAA. Either selecting a plastics coating which does not inhibit adherence of the PAA to the inner container wall or applying an otherwise appropriate plastics coating to the exterior container wall defeats the purpose of the invention, that is to prevent adherence of the PAA to the inner wall of the aerosol container, thereby assuring proper administration of the PAA to the user.

### **The Prior Art**

Applicants submit that Gennaro is a "general" reference concerning aerosol packaging, in general, and neither teaches nor suggests Applicants' invention. As noted by the Examiner, Gennaro discusses plastics coatings in aerosol applications at page 1673, column 2 thereof. However, the application of the plastics coatings suggested in Gennaro and the purposes for which the coatings are used are distinguishable from Applicants' coatings and the purposes for the use thereof. For instance, in the context of glass aerosol containers (paragraphs 1-4), Gennaro teaches using coatings for purposes of preventing deleterious effects of UV-light on the PAA, and safety, e.g. protection from flying glass in the event of glass shattering when the container is accidentally broken. The coating presumably is applied to the external surface of the glass aerosol container, else the safety aspects of the coating application be defeated. Additionally, as the film is applied to the external wall of the container, there is no teaching or suggestion as to interaction

between the coating, propellant and PAA, which interaction forms the basis for Applicants' invention. Gennaro specifically does not recommend glass aerosol containers for application of suspensions which contain PAA and gas propellant.

Gennaro also discusses plastics coatings in context of aluminum containers (paragraph 5). In context of aerosol formulations which contain only active ingredient and propellant, Applicants respectfully submit that Gennaro suggests that plastic coatings on the inner wall of the aerosol container are not required. While Gennaro does disclose aluminum aerosol containers which may contain internal coatings from epon- or epoxy-type resins, Applicants respectfully submit that Gennaro does not teach or suggest the interaction between the coating, the propellant and the PAA and thus cannot appreciate that internal coatings must inhibit deposition of the PAA on the inner container wall.

Based on the foregoing, Applicants respectfully submit that Gennaro does not appreciate the problems associated with replacement of the fluorochlorohydrocarbon propellants with alternative gas propellants, those being deposition of the PAA onto the inner walls of the aerosol container. Accordingly, Applicants respectfully submit that Gennaro neither teaches nor suggests the solution to those problems, that being Applicants' invention.

Applicants respectfully submit that Stetz et al. fails to cure the deficiencies of Gennaro, in that Stetz fails to suggest or teach that, where fluorochlorohydrocarbon propellant gases are replaced with alternative propellant gases such as fluorohydrocarbon propellants, one must apply to the inner wall of the aerosol container a plastic coating which inhibits deposition of the PAA thereon. In fact, Stetz is silent as to plastic coatings altogether and therefore can add nothing to the teachings of Gennaro with respect thereto.

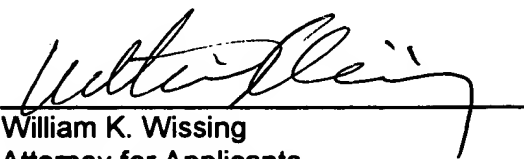
Applicants respectfully request that the Examiner consider the dependent claims individually in view of the cited art. For instance, the plastics coatings of Claim 2 comprise polytetrafluoroethylene or perfluoroethylenepropylene. Nowhere does Gennaro or Stetz suggest the use of such coatings on inner container walls to prevent adherence of the PAA thereto. Claims 9 and 12 require that the propellant consist essentially of fluorohydrocarbons. Nowhere does Gennaro or Stetz suggest an aerosol container which comprises a PAA, a propellant consisting essentially of the fluorohydrocarbon and a plastic coating applied to the inner wall of the container which inhibits adherence of the PAA thereto.

Based on all of the foregoing, Applicants respectfully submit that neither Gennaro nor Stetz, alone or in combination, teach or suggest an aerosol container system for metering and administering pharmaceutically active aerosols in the form of suspensions of PAA and a propellant gas which is free of fluorochlorohydrocarbons, which container has applied to the inner wall

thereof a plastic coating which inhibits the PAA in the suspension from depositing thereon. Accordingly, Applicants respectfully request that the rejection of Claims 2-15 under 35 U.S.C. 103 over Gennaro in view of Stetz et al. be withdrawn and a notice of allowance of the claims be issued.

Respectfully submitted,

Novartis Corporation  
Patent and Trademark Dept.  
59 Route 10  
East Hanover, NJ 07936  
(908) 277-5306

  
William K. Wissing  
Attorney for Applicants  
Reg. No. 34,757

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